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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,093	02/26/2002	Jeffrey J. Shea	10557/266546	5422

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CHIEF PATENT COUNSEL  
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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/083,093

Applicant(s)

SHEA ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 13-18, 25-27 and 29-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 13-18, 25-27 and 29-45 is/are rejected.
- 7) ☒ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

The supplemental amendment filed on November 20, 2006 has been entered.

### ***Claim Objections***

Claims 38 and 44 are objected to because of the following informalities.

In line 2 of claim 38, -- a -- should be inserted after "of" and before "bone" to correct a minor typographical error.

In line 12 of claim 44, -- the -- should be inserted after "at" and before "cylindrical" to correct a minor typographical error.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article.21(2) of such treaty in the English language.

Claims 1-2, 4-7, 10, 13-16, 18, 27, 29, 31, 33-39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchetti et al. (US 5,156,625).

Marchetti et al. disclose an implantable prosthesis including: a metal shell or "prosthetic component" 3; at least one opening extending from a first surface to the second surface of component 3, the opening having a nonthreaded frustoconical upper portion and a lower portion; a screw or "insertion member" 14 with a rounded non-frustoconical contact surface that contacts the frustoconical taper section of the opening

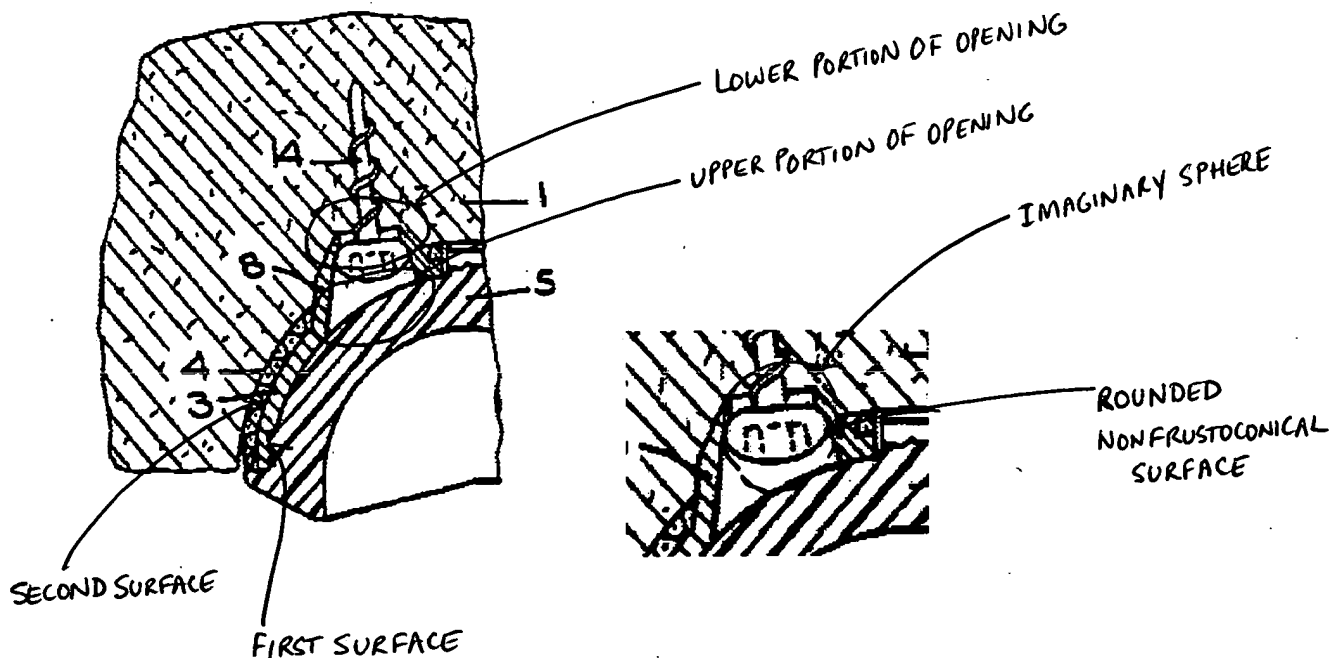
and does not contact the lower portion of the opening (Fig. 4, col. 2, lines 39-68 and col. 3, lines 1-44). See marked up Fig. 4 from Marchetti et al. below.

Regarding the limitation, "in a substantially fluid tight relationship" it is noted that the head of screw 14 forms a seal by the head of the screw abutting against the conical surface of the opening. Turning to Applicants' specification to determine what constitutes a "substantially fluid-tight seal," at page 23, line 21 and page 24, lines 1-2, Applicants' disclose that a head of an insertion member should be received and locked in a screw hole to provide "at least a partial seal." The screw 14 of Marchetti et al. forms "at least a partial seal" by being received and locked in the opening and thus fits in the opening in a "substantially fluid tight" relationship.

Regarding claims 6, 35 and 42, the rounded surface of the head of insertion member 14 is part of a sphere or "imaginary sphere" as shown in marked up Fig. 4 below.

Regarding claim 7, once inserted into the opening and locked against the inner wall of the opening, the head of screw 14 maintains a constant point of contact with the inner wall, i.e., is locked in one position with respect to the wall.

Regarding claim 37, it is noted that the head of screw 14 abuts on the conical inner wall and thus provides a liquid-tight seal in that there is no opening or gap at the locking interface.



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The method steps of claim 27, 29, 31 and 33-38 are performed when the Marchetti et al. device is used to replace the socket of a hip joint during total or partial hip joint replacement surgery.

Claims 1-8, 10, 13-18, 25-27 and 29-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Oehy et al. (US 5,645,606).

Oehy et al. disclose an acetabular shell or cup 5 having: a first surface, a second surface oriented toward bone; openings 12 extending from the first surface to the second surface wherein each opening 12 has an extended nonthreaded frustoconical taper section 25, a rounded section with a concave surface 25a beginning at a narrow end of the frustoconical section; each opening 12 capable of receiving any type of fastening element or insertion member; an insertion member 14 having a head with a spherical undersurfaces 14a seatable in surface 25a in a plurality of angular positions (Figs. 1-2, col. 2, lines 45-67, col. 3 and col. 4, lines 1-6).

Regarding claims 17, 26 and 30, Oehy et al. disclose that their acetabular prosthesis including an outer shell 5 and an inner shell or "liner" 6 is used as a joint socket 2 in a hip joint prosthesis wherein a joint head 3 is fastenable in a femur by a shank part or "stem" and articulates with joint socket 2 (Fig. 2 and col. 2, lines 28-31).

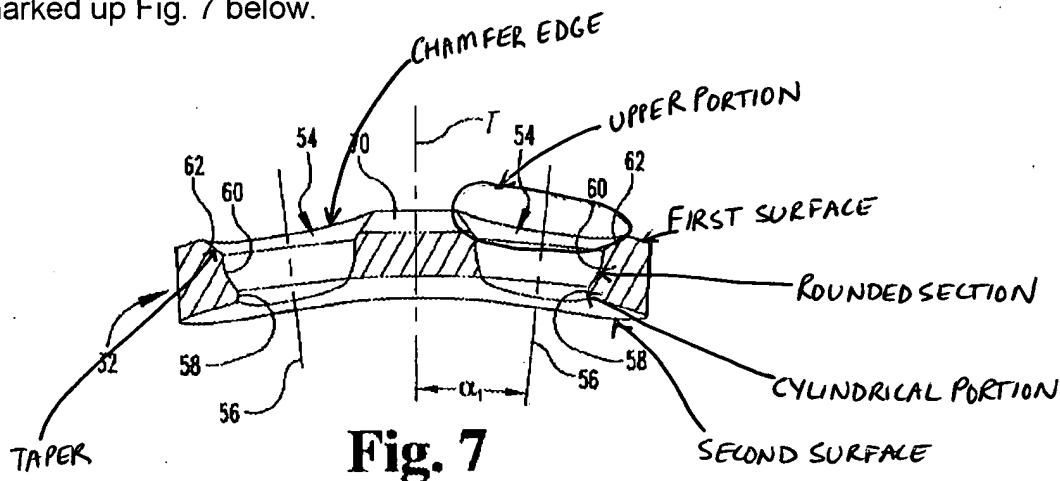
The method steps of claims 27 and 29-38 are performed during use of the Oehy et al. acetabular prosthesis in a hip joint prosthesis for hip arthroplasty.

Claims 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Justis et al. (US 6,293,949).

Justis et al. disclose a device or "implantable prosthesis" 20 including: a prosthetic component 22 having first and second surfaces; at least one opening 54 extending from the first surface to the second surface; each opening 54 further including a chamfer edge, an upper portion with a taper, a rounded section and a cylindrical portion; and wherein the rounded section has a smaller diameter than the conical taper

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(Figs. 1, 7 and 8, col. 4, lines 31-45, col. 5, lines 26-49 and col. 8, lines 33-58). See marked up Fig. 7 below.

**Fig. 7**

It is noted that the upper portion extends through a large part of the thickness of the plate and thus meets the limitation, "substantial portion" of the opening.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 17 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchetti et al. (US 5,156,625) in view of Muller (US 4,792,337).

Marchetti et al. disclose a acetabular prosthesis including a shell 3 and a liner 5 (Fig. 1).

Marchetti et al. disclose all elements of the claimed invention except for: (1) a hip replacement system; and (2) a femoral stem or femoral component or femoral prosthesis.

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Muller teaches that in total joint replacement surgery, prosthetic ball and socket components are both implanted, namely, a femoral stem component having a head or ball thereon to replace the natural femoral head is affixed to the femur and a socket or acetabular component having a shell and a liner received in a cavity of the shell is affixed to the acetabulum with the head or the ball of the femoral component rotatably or movably received in a socket of the liner to recreate the natural articulation of the hip joint. (Fig. 1, col. 1, lines 5-17 and col. 3, lines 6-11).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a femoral stem component to replace the natural femoral head for use with the Marchetti et al. device, as taught by Muller, during total hip joint replacement surgery, since it was well known in the art to use a acetabular component with a femoral component for total hip joint replacement surgery to recreate the natural articulation of the hip joint.

The method steps of claim 30 are rendered obvious by the above discussion.

### ***Response to Arguments***

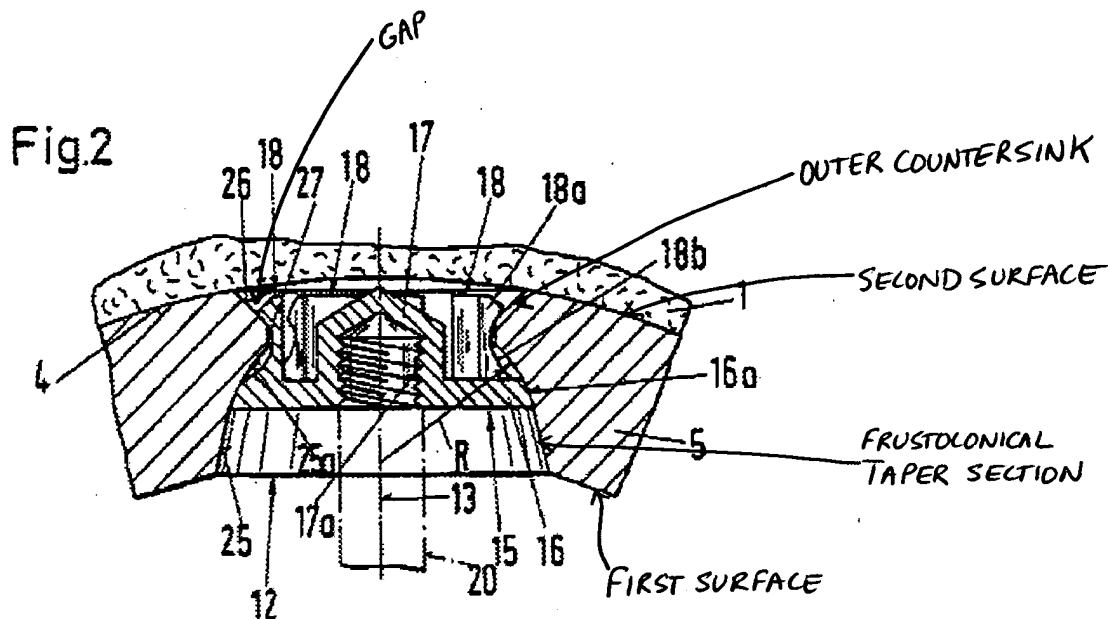
Applicants' arguments submitted under "REMARKS" in the response filed on November 20, 2006 have been fully considered.

Applicants' amendments to the specification and the drawings have been approved and entered by the Examiner.

On pages 18 and 19 of the "REMARKS" section, Applicant argues that "the entire head of the Oehy fastener sits down in the lower rounded portion of the opening and there is no part of the Oehy et al. fastener that contacts the upper portion of the opening but does not contact a lower portion of the opening."

The Examiner notes that Oehy et al. clearly disclose that opening 12 receives a screw 14 and permits angular positioning of screw 14 in opening 12 (Fig. 2, col. 2, lines 54-65 and col. 3, lines 10-18). It is the Examiner's position that depending on the angular position of screw 14 in opening 12, the spherical surface 14a of the screw head would contact and be locked relative to frustoconical surface 25 in a manner similar to

Applicants' invention (Fig. 5). Further, head 14a does not contact the lower portion, namely, outer countersink 26. See marked up Fig. 2 from Oehy et al. below.



On page 19 of the "REMARKS" section, Applicants further state that "the lower portion provides a place for a non-locking screw to be received,... but the lower portion is not what locks or receives the spherical head. The upper tapered portion is what locks the insertion member in a fluid tight or mechanically locked relationship." It appears that Applicants' are trying to claim the configuration of Fig. 6 of their invention wherein the nonfrustoconical contact surface of the insertion member head only contacts the frustoconical contact surface of the opening and does not contact the rounded surface in the opening. Applicants' arguments are directed to unclaimed features, since Applicants' are claiming that the rounded nonfrustoconical contact surface of insertion member head 14a contacts the frustoconical taper section and does not contact a lower portion of the opening. As discussed above, Oehy et al. clearly disclose this aspect of the claimed invention.

On page 20, Applicants' argue that Oehy et al. does not disclose "a gap between the second surface of the prosthetic component and a bottom of the insertion member head." It is the Examiner's position that there is a gap due to the outer counter-sink 26.

On page 20, Applicants' further argue that the Oehy et al. reference does not show or describe an insertion member with a "rounded, nonfrustoconical contact surface that contacts the frustoconical taper of the opening when locked relative to the frustoconical taper." As discussed above, in one of the plurality of angular positions of screw 14 in opening 12, the rounded surface of head 14a of insertion member 14 would contact frustoconical surface 25 and rounded portion 25a, in a manner similar to the configuration of Fig. 5 of Applicants' invention.

For the above reasons, Oehy et al. still anticipates claims 1-8, 10, 13-18, 25-27 and 29-43.

#### ***Allowable Subject Matter***

Claim 46 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter. None of the prior art either alone or in combination, teaches, discloses or suggests, an implantable prosthesis including: a prosthetic component having first and second surfaces, at least one opening extending from the first surface to the second surface, the opening including a chamfer edge, an upper portion including a conical taper, a lower portion including a rounded section and a cylindrical portion, wherein (i) the chamfer edge is formed where the opening meets the first surface; (ii) the chamfer edge meets the upper portion and the conical taper of the upper portion extends through a substantial portion of the opening; (iii) the upper portion meets the lower portion at a narrow end of the conical taper; (iv) the rounded section of the lower portion having a smaller diameter than the conical taper; and an insertion member having a head with a spherical contact surface that contacts the conical taper of the upper portion when locked relative to the taper and does not contact the lower rounded section of the opening when the insertion member is inserted into the opening.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
March 4, 2007

A handwritten signature in black ink, appearing to read "Anuradha Ramana", is written diagonally across the lower right portion of the page.